510(k) SUMMARY

K070100

General Information

Submitted by:

Haselmeier Sàrl
5 route de St Cergue
CH-1295
Mies
Switzerland

MAR 21 2007

Contact Person:

Robert J. Kilgore
Haselmeier USA
517 Benfield Road
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Severna Park, MD 21146-2596

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Date Prepared: March 5, 2007

Device Name

Trade Name: Haselmeier Pen
Common Name: Autoinjector, Pen Injector
Classification Name: Syringe Needle Introducer, Piston syringe
21 CFR 880.6920, 21 CFR 880.5860

Predicate Device

Manufacturer	Product Name	510(k) No.
SHL Medical, USA	DAI-R™ Autoinjector	K060141
Disetronic Medical System	Disetronic Pen	K982966
Eli Lilly and Company	HumaPen and HumaPen Ergo	K982842

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Device Description

The Haselmeier Pen is a self injection device for use as a reusable multiple dose delivery system for subcutaneous injections of FDA-approved drugs and biologics. A cartridge is loaded into the barrel of the pen and a needle attached. The user sets the dose required and delivers the dose by pressing down on the top of the dose button. After injection, the needle is removed from the pen and discarded.

The device is compatible with commercially available pen needles (supplied separately) that comply with: ISO 11608-2 2000 Pen-injectors for medical use - Part 2: Needles - Requirements and test method and 3-ml ISO type A cartridges (supplied separately), which meet ISO 11608-3 2000 Pen-injectors for medical use - Part 3: Finished cartridges - Requirements and test methods, with the following dimensions:

Overall cartridge length including aluminum cap:	63.9 mm ± 0.3 mm
Outside Cartridge Diameter:	11.94 mm MAX.
Inner Cartridge Diameter:	9.65 mm ± 0.1 mm measured at open end.
Maximum eccentricity of aluminum cap:	0.33 mm

Intended Use

The Haselmeier Pen is a hand-held mechanical device intended for the subcutaneous, self-administration of FDA-approved drugs and biologics. The Haselmeier Pen is designed to be used with 3.0 mL cartridges which are prefilled prior to an injection. The Haselmeier Pen is for use in the home environment to aid and support prescribed treatment and therapy.

Technological Comparison

The Haselmeier Pen has similar indications for use to the DAI-R™ Autoinjector and is similar in design and operating principle to the Disetronic Pen, HumaPen, and HumaPen Ergo.

Testing

The Haselmeier Pen has been demonstrated to perform as intended.

Conclusions

The Haselmeier Pen is substantially equivalent to legally marketed devices (autoinjectors and pen injectors).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert J. Kilgore
Director
Haselmeier USA
517 Benfield Road, Suite 301
Severna Park, Maryland 21146-2596

MAR 2 1 2007

Re: K070100
Trade/Device Name: Haselmeier Pen
Regulation Number: 21 CFR 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: March 5, 2007
Received: March 5, 2007

Dear Mr. Kilgore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

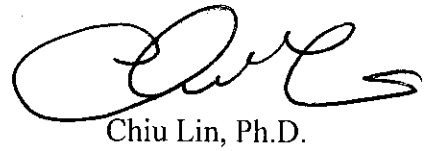
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K070100

Device Name: Haselmeier Pen

Sponsor Name: Haselmeier Sàrl

Indications for Use:

The Haselmeier Pen is a hand-held mechanical device intended for the subcutaneous, self-administration of FDA-approved drugs and biologics. The Haselmeier Pen is designed to be used with 3.0 mL cartridges which are prefilled prior to an injection. The Haselmeier Pen is for use in the home environment to aid and support prescribed treatment and therapy.

Prescription Use ☒ (21 CFR 801 Subpart D) Or Over-The-Counter Use ☐ (21 CFR 807 Subpart C)

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman for ADW 3/21/07

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